DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
(AMENDED)

FLA-05-30

April 18, 2005

Joseph L. Molina, President
Jowdy Industries, Inc.
d/b/a Independent Seafoods
5300 Georgia Avenue
West Palm Beach, Florida 33405-3520

Dear Mr. Molina:

2005 new 1/10/06

On January 4-10, 2004, the United States Food and Drug Administration (FDA) conducted an inspection of your facility located at the above listed address. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control points (HACCP) regulations, Title 21 Code of Federal Regulations, (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your seafood products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed deviations from the seafood HACCP regulations. The FDA Investigator provided your vice president, Miguel E. Molina, with a copy of the form FDA 483 (copy enclosed), which represents the investigator's preliminary evaluation of your firm's performance regarding various aspects of the HACCP requirements. After additional review, we determined that the deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for cooking of lobsters to control the hazards of pathogen survival and growth.

   In addition, your firm does not have a HACCP plan for vacuum packaged refrigerated mahi mahi and frozen vacuum packaged tuna to control the food safety hazard of *Clostridium botulinum*. Vacuum packaging of seafood products increases the risk of *C. botulinum* outgrowth which must be controlled in order to avoid the production of toxin.

If refrigeration is the sole barrier to toxin formation, FDA recommends strict temperature control and monitoring during transport and storage. These same recommendations apply during thawing of vacuum packaged frozen seafood.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for:

   - "All Shellfish Products" does not list a hazard of pathogen survival and pathogen growth and toxin formation for the lobsters that you cook. Further, it does not list a hazard of pathogen growth and toxin formation, including *Clostridium botulinum* toxin formation, for your canned crabmeat. FDA recommends that you have separate plans for products with different hazards.

   - "Mahi, Wahoo, Amberjack, Tuna, Anchovy, Bluefish, Mackerel, Marlin, Sardine and Roe" does not list the food safety hazard of parasites in amberjack, grouper and mackerel and your HACCP plan for "Amberjack, Grouper, Hogfish, Mackerel Spanish, Parrotfish, Pompano, Certain Snapper" does not list a food safety hazard of parasites for amberjack, and hogfish.

3. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for scombroid fish lists a monitoring procedure of "Visual check of ice covered two times during operation" at the "Iced Storage" critical control point that is not adequate to control the hazard of histamine formation during the times when product is in the cooler, but the firm is not operating.

4. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of "visual check of continuous temperature recorder" at the "Dry cooler storage" CCP to control pathogen growth and toxin formation as listed in your HACCP plan for "All Shellfish Products." Our investigator observed that you do not have a continuous temperature recorder in the dry cooler. FDA recommends periodic monitoring of ice or coolant or continuous monitoring of temperature to control the hazard of pathogens in products that will not be thoroughly cooked prior to consumption.

5. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Storage" critical control point to control histamine formation listed in your HACCP plan for scombroid species fish. Records revealed that the temperature of the cooler was checked only once on Saturdays since 10/13/2003.

6. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor:

Safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice, prevention of cross-contamination from insanitary objects [21 CFR 123.11(b)(1) and (3)] as evidenced by:

a) Ice used in direct contact with cooked lobsters, cooked stone crab claws, live shellfish and raw seafood was obtained from an ice-making machine that had an opening on the top which exposed the water/ice to outside contaminants (birds, insects, rain etc); the other ice machine had a build up of tar and filth, and the reservoir did not have a lid to protect the water from contamination and the top of the ice machine contained frozen rags and debris.

b) There were no backflow prevention devices on the hose bibs in the processing room.

Protection of food, food packaging material, and food contact surfaces from adulteration [21 CFR 123.11(b)(5)] as evidenced by:

c) Plastic bags and cardboard cartons used for food packaging as well as employee freezer coats were stored without protection.

Prevention of cross-contamination from insanitary objects to food [21 CFR 123.11(b)(3)] as evidenced by:

d) An employee who was pin-boning salmon was observed wearing a band-aid on his index finger of his ungloved left hand.

e) Condensate was dripping from refrigeration units onto iced fish and stone crab claws in the cooler.

f) The shovels used in the plant are not dedicated to food or non-food contact. The same shovels were observed being used for ice to cover fish (ready to eat and raw), as were used to scoop fish debris into trash bins in the plant and outside the plant.

g) The ice room in the processing area did not contain a threshold or other barrier to protect it from entering the processing area;; workers routinely walked into the ice room wearing the same boots they used throughout the plant.

Condition and cleanliness of food-contact surfaces, including utensils, gloves and outer garments [21 CFR 123.11(b)(2)] as evidenced by:

h) The lobster steamer was observed dirty, and the tray contained dirty liquid on 1/4/05. It was used on Monday 1/3/05, but was not cleaned after use.

i) There was no measurable sanitizer in the processing room clean utensil soak tub or knife sanitizer buckets on 1/4-5/2005.

Maintenance of hand washing facilities [21 CFR 123.11(b)(4)] as evidenced by:

j) There was no hot water at the hand sink in the processing room on 1/4/05 or 1/5/05.

Exclusion of pests from the processing room [21 CFR 123.11(b)(8)] as evidenced by:

k) An insecticutor was observed near the entrance to the refrigerated processing room across from the lobster steamer. The insecticutor catch tray was hanging loose and contained a collection of dead flies.

7. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records on January 4-5, 2005 for the safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice, prevention of cross-contamination from insanitary objects, protection of food, food packaging material, and food contact surfaces from adulteration, and control of employee health conditions.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and /or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within 15 working days from your receipt of this letter of the specific steps you have taken to correct these violations including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason or the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Virginia L. Meeks, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Meeks at (407) 475-4731. We look forward to working with you to achieve a successful HACCP program.

Sincerely,

Emma R. Singleton
Director, Florida District

Enclosure
FDA 483 (Inspectional Observations)